

COVID-19 Vaccine Information Brief

January 5, 2021

Changes to the document from the previous version are highlighted in yellow.

Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine

CDC has released updated clinical guidance related to mRNA vaccines. The updated guidance can be found at [Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine | CDC](#).

The updated guidance includes:

- Additional information on antibody therapies and COVID-19 vaccination
- Information on COVID-19 vaccination and outbreak management
- Additional information on vaccination of immunocompromised persons
- Updates to contraindications and precautions to vaccination
- Information on COVID-19 vaccination and tuberculin skin testing

Major updates include:

- Defining an immediate allergic reaction as “any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.”
- Identifying contraindications to either of the mRNA COVID-19 vaccines as:
 - Severe allergic reaction (e.g, anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
 - Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])
 - Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)
- Expanding precautions to mRNA COVID-19 vaccines to include not only anaphylaxis but also any previous immediate allergic reaction to any other vaccine or injectable therapy
- Includes observation periods after vaccination as 30 minutes for any persons with a precaution to vaccination or a history of anaphylaxis due to any cause and 15 minutes for all other persons

CDC is working to update its current documents to reflect the new guidance including the screening tool.

Additional Doses of COVID-19 Vaccine per Vial

The Food and Drug Administration (FDA) has advised it is acceptable to use every full dose of COVID-19 vaccine obtainable from each vial of vaccine. However, since the COVID-19 vaccines do not contain preservatives, it is critical to note any further remaining vaccine that does not constitute a full dose should not be pooled from multiple vials to create a dose. [IRIS instructions](#) are available to determine if additional vaccine inventory adjustments are required. Contact the IRIS Help Desk at 800-374-3958 with questions regarding vaccine inventory.

Emergency Use Authorization (EUA) - Moderna COVID-19 Vaccine

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of Moderna COVID-19 Vaccine for active immunization in individuals 18 years of age and older.

- [Letter of Authorization](#)
- [EUA Fact Sheet for Healthcare Providers Administering Vaccine](#)
- [EUA Fact Sheet for Vaccine Recipients and Caregivers](#)

Moderna Clinical Guidance

- Moderna Call Center - available 8am to 8pm EST, Monday-Friday @ 1-866-663-3762
 - [Moderna COVID-19 Vaccine webpage](#) - provides specific information to Moderna's vaccine, including resources to assist providers in storing, handling, determining the expiration date of each lot of vaccine, dosing and administering the vaccine.
 - [Interim Clinic Considerations for Use of Moderna COVID-19 Vaccine](#)
 - [Moderna COVID-19 Vaccine Preparation and Administration Summary](#)
 - [Freezer Temperature Log- Fahrenheit](#)
 - [Freezer Temperature Log- Celsius](#)
 - [Translations of EUA Fact Sheet for Recipients and Caregivers](#)
 - [COVID-19 Vaccine Clinical FAQs](#)
 - [Expiration date tracker](#)
 - [Beyond use date tracking labels for refrigerator storage](#)
 - [Vaccine storage and handling summary](#)
 - [Vaccine storage and handling labels](#)
-

Pfizer Clinical Guidance

- Pfizer Call Center - available 8am to 8pm EST, Monday-Friday @ 1-800-438-1985
- [Pfizer-BioNTech COVID-19 Vaccine webpage](#) - provides specific information to Pfizer's vaccine, including resources to assist providers in storing, handling, and administering the vaccine.
- [Interim Clinic Considerations of Use of Pfizer COVID-19 Vaccine](#)
- [Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites](#)

- [Pre-Vaccination Screening Form for Pfizer COVID-19 Vaccine](#)
- [Pfizer COVID-19 Vaccine Preparation and Administration Summary](#)
- [Ultra-Cold Temperature Log- Fahrenheit](#)
- [Ultra-Cold Temperature Log - Celsius](#)
- [Pfizer On Demand Training](#) - self-paced training module for healthcare professionals administering Pfizer COVID-19 vaccine. Continuing education is available.

Emergency Use Authorization (EUA) - Pfizer

The FDA reissued letter of authorization (LOA) and revised fact sheets for providers and recipients on December 23. FDA also updated the FAQ page to include information on the additional dose, as well as other information on the reissued LOA.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of Pfizer-BioNTech COVID-19 Vaccine for active immunization in individuals 16 years of age and older.

- [Letter of Authorization](#) - Updated
- [EUA Fact Sheet for Healthcare Providers Administering Vaccine](#)
- [EUA Fact Sheet for Vaccine Recipients and Caregivers](#)
- [Translations of EUA Fact Sheet for Recipients and Caregivers](#)
- [Pfizer FAQs](#)

[CDC COVID-19 Vaccination Information for Consumers](#)

- [What to expect at your vaccination appointment](#)
- [What to expect after getting vaccinated](#)
- [Benefits of Getting a COVID-19 Vaccine](#)
- [How COVID-19 Vaccines Work](#)
- [Myths and Misconceptions about COVID-19 Vaccines](#)
- [Frequently Asked Questions about COVID-19 Vaccination](#)

V-safe After Vaccination Health Checker

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after an individual receives a COVID-19 vaccination. V-safe web pages feature information on how to register and complete a v-safe health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support. These web pages will be continuously updated with additional resources.

- V-safe information sheet and poster: Posted on the Vaccine webpage and available in 5 languages: English, Spanish, Korean, Vietnamese, and Simplified Chinese
- [V-safe after vaccination health checker website](#)

CDC COVID-19 Vaccination Resources

- [COVID-19 Vaccination Planning resources for healthcare professionals](#)
- [Frequently Asked Questions about COVID-19 Vaccination](#)
- [COVID-19 Vaccines and Severe Allergic Reactions](#)
- [Vaccination Considerations for People who are Pregnant or Breastfeeding](#)
- [CDC COVID-19 Vaccine Website](#)
- [COVID-19 ACIP Vaccine Recommendations](#)
- [Toolkit for Medical Centers, Clinics, and Clinicians](#)
- [Engaging in Effective COVID-19 Vaccine Conversations](#)
- [Toolkit for Medical Centers, Clinics, and Clinicians](#)
- [Answering Patient Questions](#)
- [Post-vaccination considerations for healthcare personnel](#)
- [Post-vaccination considerations for long-term care residents](#)
- [Ensuring COVID-19 Vaccines Work | CDC](#)
- [Facts about COVID-19 Vaccines](#)
- [How CDC Is Making COVID-19 Vaccine Recommendations | CDC](#)
- [Vaccine Education and Training for Healthcare Professionals | CDC](#)
- [COVID-19 Vaccination Resources](#)
- [COVID-19 Vaccine Training Module for Healthcare Providers](#)
- [Best Practices on Vaccine Storage and Handling](#)
- [Different COVID-19 Vaccines](#)

IDPH COVID-19 Vaccination Resources

- **Iowa Department of Public Health Statewide Standing Order for COVID-19 Vaccination**
 - The Standing Order has been updated as of December 30, 2020. This has been sent to enrolled COVID-19 Vaccine Providers and is available on the HAN.
 - Standing Order remains in effect in the State of Iowa until rescinded or until December 31, 2021
- [IDPH COVID-19 Vaccine Website](#) - Includes web-based training courses, videos, job aids and references regarding vaccine administration, general best practice guidelines for immunizations and vaccine storage and handling.
- [Administration of COVID-19 Vaccine - County/State of Residence Guidance](#) - This memo outlines the administration of COVID-19 vaccine by Iowa healthcare organizations to individuals regardless of permanent place of residence (county or state) or where the individual is seeking vaccination. In addition, receipt of COVID-19 vaccine does not require proof of U.S. citizenship. This is also available on HAN.
- [Iowa Department of Public Health Vaccine Shortage Order](#) - Iowa Healthcare providers shall only vaccinate persons who are included in a priority designation which has been activated by IDPH. Healthcare providers are prohibited from vaccinating any persons not included in a priority designation.

- **Consent Form Sample** - The Federal Government does not require consent for the administration of COVID-19 vaccine. This document has been emailed to all enrolled COVID-19 Vaccine Providers and is available on HAN.
- **Declination Form Sample** - A sample declination form is available to assist partners in the development of organization specific forms. This document has been emailed to all enrolled COVID-19 Vaccine Providers and is available on HAN.
- **Infectious Disease Advisory Council (IDAC)** - Iowa's Infectious Disease Advisory Council provides recommendations to the IDPH Director and Medical Director in developing COVID-19 vaccine distribution. [Phase 1A Recommendations](#) and a summary of voting has been posted to the [IDAC webpage](#).
- **IDPH Billing Memo** - A guidance document for COVID-19 Vaccine Cost, Billing, and Reimbursement has been posted to the IDPH Vaccine webpage.
- *IDPH FAQs will no longer be updated. Each manufacturer has FAQs related to COVID-19 vaccine as well as CDC's Frequently Asked Questions about COVID-19 vaccination. Links to these resources are found above.*

MMWRs and Interim Guidance

- On December 20, 2020 an MMWR article titled, [“The Advisory Committee on Immunization Practices’ Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States, December 2020”](#) was published.
 - On December 13, 2020 an MMWR article titled, [“The Advisory Committee on Immunization Practices’ Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020”](#) was published.
 - On December 13, 2020 an MMWR article titled, [“The Advisory Committee on Immunization Practices’ Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020”](#) was published.
 - On December 3, 2020 an MMWR article titled, [“The Advisory Committee on Immunization Practices’ Interims Recommendation for Allocating Initial Supplies of COVID-19 Vaccine - United States, 2020”](#) was published.
 - The [“Interim Considerations for COVID-19 Vaccination of Healthcare Personnel and Long-Term Care Facility Residents”](#) was released.
 - On November 23, an MMWR article titled [“The Advisory Committee on Immunization Practices Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine - United States, 2020”](#) was published.
-

IDPH COVID-19 Vaccine Information Resources

- **COVID-19 Vaccine Call Center** - IDPH has established a healthcare provider COVID-19 Vaccine Call Center. To reach the COVID-19 Vaccine Call Center, call **1-800-831-6293, Option 1**.
 - **COVID-19 Vaccine Email** - IDPH has set up a COVID-19 Vaccine Email to respond specifically to questions from healthcare providers regarding COVID-19 vaccine. Vaccine questions can be emailed to: COVID19Vaccine@idph.iowa.gov.
 - **COVID-19 Call Center for the General Public** - Questions from the general public regarding COVID-19 vaccines can be directed to 211.
-

COVID-19 Vaccine Planning

- **Pharmacy Partnership for Long-term Care (LTC) Program** - CDC is partnering with Community Pharmacy, CVS and Walgreens to offer on-site COVID-19 vaccination services for residents of nursing homes and assisted living facilities. Facility staff will also be vaccinated with COVID-19 vaccine as part of this partnership. Information regarding the program can be found on the HAN Document Library, Pharmacy Partnership for LTC Program folder.
 - Pharmacies began vaccinating both SNF & ALF (residents and staff) on 12/28/2020
-

VaccineFinder

- IDPH will report vaccine inventory to [VaccineFinder](#) for all Iowa enrolled COVID-19 vaccine providers. It is important for all providers to maintain an accurate vaccine inventory of COVID-19 vaccines in IRIS to allow for accurate reporting.
 - Optional: Providers may choose to make their location(s) visible on the public-facing VaccineFinder website to increase access to vaccines once supply is available to the public. This does ***NOT*** replace reporting doses administered to IRIS within 24 hours of administration.
-

Federal Pharmacy Partnership Strategy for COVID-19 Vaccination Program

- HHS is partnering with pharmacies to increase access to COVID-19 vaccine supply increases and vaccines are recommended beyond the initial populations. Pharmacy partners will sign the COVID-19 Vaccination Program Provider Agreement at the federal level.
- Pharmacy partners will directly order and receive allocation of COVID-19 vaccine from the federal government. Timing and scale of activation (how many partners, how many stores) will depend on various factors, including vaccine supply.
- Activation based on a national scale, with select pharmacy partners directly ordering COVID-19 vaccine from CDC.
- Pharmacy partners must report COVID-19 vaccine inventory in each store via VaccineFinder and report COVID-19 vaccine doses administration to IRIS.